9200/2576

2576

PATENT
Attorney Docket No. 1147.0142

#3 B. Webb 8/2/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of:)
U.S. Patent No. ~~5,570,338~~ 5750338)
Mark L. Collins et al.)
)
Reissue Serial No.: Unassigned) Group Art Unit: Unassigned
)
Reissue Application Filed: Herewith) Examiner: Unassigned

For: TARGET AND BACKGROUND CAPTURE METHODS WITH AMPLIFICATION FOR AFFINITY ASSAYS

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

NOTICE OF RELATED LITIGATION

Through its legal representative, the Patent Owner wishes to notify the U.S. Patent and Trademark Office that U.S. Patent 5,750,338 (the '338 patent) entitled "Target and Background Capture Methods with Amplification for Affinity Assays," filed for reissue on March 8, 2000, is involved in litigation. Nonetheless, the Patent Owner expressly requests that the reissue application be examined at this time. Moreover, on March 9, 2000, the Patent Owner filed a motion to stay the litigation pending resolution of reissue proceedings. A copy of this motion is attached. As soon as the Patent Owner receives a decision on this motion, the Patent Owner will notify the Patent Office.

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000

The status of the litigation is as follows. A Complaint for Declaratory Relief was filed by a licensee of the '338 patent on December 22, 1999, alleging that the '338 patent was invalid. On January 6, 1999, the licensee provided to the Patent Owner six prior publications in support of their contention of invalidity. The Patent Owner informed the licensee of its intention to answer the complaint on January 19, 2000, and on January 25, 2000, the licensee filed an Amended Complaint further alleging unfair competition of the part of the Patent Owner. As noted above, the Patent Owner filed its Motion to Stay on March 9, 2000, and also moved to dismiss the unfair competition claims.

In accordance with its duty to provide the Patent Office documents from the litigation that are material to patentability, the Patent Owner hereby encloses copies of its Motion for a Stay of Proceedings, the Memorandum in support of that motion, and the supporting Declaration, as well as copies of the licensee's Complaints. Copies of Exhibits A-F identified in the Memorandum have not been included because they are redundant, to the extent pertinent to patentability, to papers filed with the petition for reissue, but the Patent Owner will provide them upon request by the Office. The six prior publications provided to the Patent Owner by the licensee have already been submitted to the Patent Office in an Information Disclosure Statement accompanying the reissue application filed on March 8, 2000, together with a Preliminary Amendment that explains why these prior art documents are not invalidating. In addition, the Patent Owner now seeks from the licensee the identity of any other references on which the

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licensee intends to base its allegations of invalidity. The Patent Owner will forward these documents to the Patent Office upon receipt.

The Patent Owner will promptly notify the Patent Office of the decision on the motion for a stay of litigation. In the meantime, the Patent Owner earnestly requests expedient examination of the reissue application.

If there are any fees due in connection with the filing of this Notice not already accounted for, please charge the fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: Jean Burke Fordis
Jean Burke Fordis
Reg. No. 32,984

Date: March 10, 2000

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Attorneys for Plaintiff
Gen-Probe Incorporated

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No. '99CV 2668H AJB

COMPLAINT FOR DECLARATORY RELIEF

DEMAND FOR JURY TRIAL

PLAINTIFF GEN-PROBE ALLEGES:

INTRODUCTION

1. This action concerns the invalidity and non-infringement of United States Patent No. 5,750,338 ("the '338 patent"). As set forth below, plaintiff Gen-Probe Incorporated ("Gen-Probe") asks this court to declare the '338 patent invalid and further to declare that Gen-Probe's current and anticipated activities do not infringe any valid claim of the '338 patent.

THE PARTIES

2. Gen-Probe was founded in San Diego in 1984 as a small "start up" company, seeking to develop products based on the discoveries of a local research scientist. Over time, Gen-Probe became one of the largest biotechnology firms in San Diego. Gen-Probe now maintains its

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principal offices and research facilities at 10210 Genetic Center Drive in San Diego, where it employs over 500 scientists and staff. Gen-Probe is organized under the laws of the State of Delaware.

3. Gen-Probe is informed and believes that defendant Vysis, Inc. (hereinafter "Vysis" or "the defendant") is a corporation organized and incorporated under the laws of the State of Delaware. Gen-Probe is further informed and believes that Vysis maintains its principal place of business in Downers Grove, Illinois and that it is controlled by BP Amoco, Inc.

JURISDICTION AND VENUE

4. Counts One and Two of this Complaint seek declaratory relief under the Declaratory Judgment Act, Title 28, United States Code, Sections 2201 and 2202. This Court has subject matter jurisdiction of the claims asserted thereunder by reason of Title 28, United States Code, Sections 1331 and 1338(a).

5. Venue is proper in this District under Title 28, United States Code, Sections 1391(a), 1391(b) and 1400(b).

BACKGROUND

6. Living cells store genetic information in molecules of nucleic acid known as DNA. These molecules consist of long, thin, chain-like strands which, in turn, are usually found in the form of two tightly bound, complementary chains. DNA molecules retain their genetic information in the form of a genetic code. The information in the DNA determines the life processes of each organism. The information in the DNA is used to make related nucleic acid molecules called RNA that cells use to manufacture proteins.

7. Through the work of its scientists and staff, Gen-Probe has developed and continues to develop diagnostic tests that seek out the DNA or RNA of the infectious organisms. These types of tests are generally referred to as "genetic probes" or "nucleic acid tests" ("NAT"). Gen-Probe now markets DNA probe products that test for a wide range of microorganisms that cause tuberculosis, strep throat, pneumonia, fungal infections and sexually transmitted diseases. Through the efforts of its scientists and staff, Gen-Probe has emerged as the recognized world leader in the development, manufacture and commercialization of diagnostic products based on its patented

genetic probe technology. Gen-Probe has received over 40 FDA clearances and approvals for genetic probe tests to detect a wide range of microorganisms, including Chlamydia, Mycobacterium tuberculosis and Neisseria gonorrhoeae.

8. Many human diseases are caused by bacterial or viral agents that invade living cells. Historically, the presence of these bacterial or viral agents was detected directly by time-consuming methods such as culture or indirectly through the detection of antibodies. Unfortunately, it takes time, sometimes weeks or months, to grow organisms in culture, and it usually takes months for the body to manufacture antibodies in sufficient amounts to reveal the presence of infectious agents. Consequently, these methods do not lend themselves to early detection of infection. NAT addresses this problem.

9. Among the disease detection technologies recently applied by Gen-Probe is its patented nucleic acid technology known as "Transcription-Mediated Amplication" ("TMA"). This technology enables Gen-Probe's NAT products to detect extraordinarily small quantities of the nucleic acids of infectious agents.

10. In September 1996, Gen-Probe received a $7.7 million grant from the National Institutes of Health to develop TMA-based nucleic acid tests to be used in screening donated blood for and human immunodeficiency virus (HIV), the causative agent of AIDS, and hepatitis C virus (HCV), which causes a severe form of hepatitis.

11. At the time of the NIH grant to Gen-Probe, donated blood was principally tested by procedures that detected the presence of antibodies to the viruses being screened. Due to the time it takes for the body to make antibodies after initial infection, donated blood may test negative for antibodies, yet still carry infectious viruses. This delay between the time of actual infection and the time that antibodies can first be detected is often known as the "window period." Reduction of this "window period" was a significant concern of the United States government and the primary focus of the grant to Gen-Probe to develop NAT diagnostics for use in blood screening.

12. In fulfilling its obligations under the grant, Gen-Probe developed NAT tests to detect the DNA of HIV and hepatitis C in blood. Through the use of its NAT test, Gen-Probe believes that researchers and medical personnel may rapidly and *directly* detect the presence of

genetic material of viruses like HIV and HCV more accurately and without the complications and delay associated with conventional *indirect* tests. As such, Gen-Probe believes that its new test may significantly reduce the "window period" for detection of these extremely harmful viral agents and resulting diseases.

13. Final development of the NAT tests for blood screening in the United States is now taking place in testing conducted by the American Red Cross, America's Blood Centers, and others. ("A Purity Quest; Local Biotech's Ultra-Sensitive Blood Screening Could Cut Risk of AIDS, Hepatitis," *San Diego Union*, March 25, 1999, page C-1.) Use of the tests in the United States is made pursuant to an Investigational New Drug Application filed with the United States Food and Drug Administration. In blood tested by the American Red Cross, Gen-Probe's products have detected hepatitis C and HIV which escaped detection by prior methods. ("New Blood Screening Finds Virus Others Missed; Experimental Test Turns Up Hepatitis C In Donated Blood," *San Diego Union*, April 2, 1999, page B-2.)

14. On September 21, 1999, the French Ministry of Health approved the sale of the Gen-Probe blood screening tests in France. Gen-Probe anticipates approval of its tests for us in Australia in early 2000.

15. Gen-Probe has entered into an agreement with Chiron Corporation ("Chiron") of Emeryville, California, with respect to the development, manufacture, and distribution of blood screening products. Gen-Probe is also a party to an agreement with Bayer Corporation ("Bayer") of Emeryville, California with respect to the development, manufacture, and distribution of clinical diagnostic products for the detection of HIV and hepatitis C, among other pathogens.

16. Gen-Probe anticipates that clinical trials in the United States of its HIV/HCV tests for use in blood screening and in clinical diagnostics will commence in the first part of 2000. Gen-Probe anticipates the conclusion of those clinical trials, and the initiation of commercial sales in the United States of kits containing its HIV/HCV blood screening test, during 2000.

17. All of the Gen-Probe products are manufactured in San Diego, California.

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THE '338 PATENT

18. Gen-Probe is informed and believes that on or about May 12, 1998, the United States Patent and Trademark Office issued United States Patent No. 5,750,338 ("the '338 patent") based upon Patent Application No. 238,080 filed on May 3, 1994.

19. Gen-Probe is informed and believes that defendant Vysis claims to be the owner, by assignment, of the entire right, title and interest of the '338 patent. The claims of the '338 patent purport to relate to assays and probes for polynucleotide molecules such as DNA and RNA.

20. In early 1999, Vysis informed Gen-Probe that it believed that the '338 patent applied to Gen-Probe's NAT blood screening tests for HIV and HCV. Following further discussions and to avoid any complications in Gen-Probe's plans for commercial deployment of its NAT test kits, as of June 22, 1999 Gen-Probe obtained a license from Vysis under the '338 patent. Gen-Probe also obtained options to licenses for its relationships with Chiron and Bayer. Under the terms of the licenses, Vysis requires Gen-Probe (and its allied parties if the options are exercised) to make significant financial payments to Vysis as royalties on the sale of any product covered by valid claims of the '338 patent.

21. Notwithstanding the existence of the licenses, and as further alleged herein, Gen-Probe believes that the '338 patent is invalid in all material respects. Furthermore, Gen-Probe believes that its NAT blood screening tests do not infringe any valid claim of the '338 patent. As such, Gen-Probe disagrees with Vysis' contention that the claims of the '338 patent "apply" to Gen-Probe's activities.

22. Gen-Probe is informed and believes that the defendant disputes and disagrees with Gen-Probe's contentions concerning the non-infringing nature of its present and planned activities and products and the invalidity of the '338 patent, as expressed above and detailed in the following paragraphs of the complaint. Furthermore, based upon a long history of litigation between Gen-Probe and Vysis' and its affiliates, Gen-Probe reasonably anticipates that should it fail to pay royalties pursuant to the Vysis license, Vysis will aggressively attempt to enforce its perceived rights under the '338 patent by terminating the license and through litigation against Gen-Probe, its allied parties, and customers.

23. An actual case or controversy exists between Gen-Probe and Vysis concerning validity and infringement of the '338 patent.

COUNT ONE

NON-INFRINGEMENT OF THE '338 PATENT

24. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 23 of this complaint.

25. Gen-Probe's NAT test kits for use in detecting HCV and HIV in the Nation's blood supply do not and will not infringe the '338 patent.

COUNT TWO

INVALIDITY OF THE '338 PATENT

26. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 23 of this complaint.

27. The '338 patent is invalid by reason of one or more provisions of Title 35 of the United States Code.

WHEREFORE, Gen-Probe prays as follows:

1. For a declaration that:

a. Gen-Probe's products do not and will not infringe the '338 patent; and

b. The '338 patent is invalid.

2. For a preliminary and permanent injunction enjoining and restraining defendant, its respective officers, agents, servants, employees and attorneys, and all persons acting in concert with them, and each of them:

a. From making any claims to any person or entity that Gen-Probe's products infringe the '338 patent;

b. From interfering with, or threatening to interfere with the manufacture, sale, license, or use of Gen-Probe's products by Gen-Probe, its allied parties, distributors, customers, licensees, successors or assigns, and others; and

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c. From instituting or prosecuting any lawsuit or proceeding, placing in issue the right of Gen-Probe, its allied parties, distributors, customers, licensees, successors or assigns, and others to make, use or sell Gen-Probe's products.

3. For recovery of Gen-Probe's attorneys' fees and costs of suit incurred herein; and

4. For such other and further relief as the Court may deem just and proper.

Dated: December 21, 1999

COOLEY GODWARD LLP
STEPHEN P. SWINTON (106398)
JAMES DONATO (146140)

By: Patrick Mahony for Steve Swinton
Stephen P. Swinton

Attorneys for Plaintiff
Gen-Probe Incorporated

DEMAND FOR TRIAL BY JURY

Gen-Probe demands trial by jury for all applicable issues arising in connection with its complaint.

Dated: December 21, 1999

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JAMES DONATO (146140)

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Stephen P. Swinton

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Attorneys for Plaintiff
Gen-Probe Incorporated

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No. 99CV2668H AJB

FIRST AMENDED COMPLAINT FOR DECLARATORY RELIEF AND UNFAIR COMPETITION

PLAINTIFF GEN-PROBE ALLEGES:

INTRODUCTION

1. This action concerns the nature and scope of any obligation of plaintiff Gen-Probe Incorporated ("Gen-Probe") to make royalty payments to defendant Vysis, Inc. ("Vysis") pursuant to a patent license agreement between the parties ("the License") in light of the invalidity and non-infringement of United States Patent No. 5,750,338 ("the '338 patent") that is a subject of that License. As set forth below, Gen-Probe asks this court to declare the '338 patent invalid and further to declare that Gen-Probe's current and anticipated activities do not infringe any valid claims of the '338 patent. As a corollary to those declarations, Gen-Probe also asks this Court to declare its rights and obligations under the terms of the parties' License. Finally, Gen-Probe also seeks relief from Vysis' continuing acts of wrongful and unfair conduct with respect to the '338 patent.

THE PARTIES

2. Gen-Probe was founded in San Diego in 1984 as a small "start up" company, seeking to develop products based on the discoveries of a local research scientist. Over time, Gen-Probe became one of the largest biotechnology firms in San Diego. Gen-Probe now maintains its principal offices and research facilities at 10210 Genetic Center Drive in San Diego, where it employs over 500 scientists and staff. Gen-Probe is organized under the laws of the State of Delaware.

3. Gen-Probe is informed and believes that defendant Vysis, Inc. (hereinafter "Vysis" or "the defendant") is a corporation organized and incorporated under the laws of the State of Delaware. Gen-Probe is further informed and believes that Vysis maintains its principal place of business in Downers Grove, Illinois and that it is controlled by BP Amoco, Inc.

JURISDICTION AND VENUE

4. Counts One and Two of this Complaint seek declaratory relief under the Declaratory Judgment Act, Title 28, United States Code, Sections 2201 and 2202. This Court has subject matter jurisdiction of the claims asserted thereunder by reason of Title 28, United States Code, Sections 1331, 1338(a), 1338(b) and 1367.

5. Venue is proper in this District under Title 28, United States Code, Sections 1391(b) and 1400(b).

BACKGROUND

6. Living cells store genetic information in molecules of nucleic acid known as DNA. These molecules consist of long, thin, chain-like strands which, in turn, are usually found in the form of two tightly bound, complementary chains. DNA molecules retain their genetic information in the form of a genetic code. The information in the DNA determines the life processes of each organism. The information in the DNA is used to make related nucleic acid molecules called RNA that cells use to manufacture proteins.

7. Through the work of its scientists and staff, Gen-Probe has developed and continues to develop diagnostic tests that seek out the DNA or RNA of the infectious organisms. These types of tests are generally referred to as "genetic probes" or "nucleic acid tests" ("NAT"). Gen-Probe

now markets DNA probe products that test for a wide range of microorganisms that cause tuberculosis, strep throat, pneumonia, fungal infections and sexually transmitted diseases. Through the efforts of its scientists and staff, Gen-Probe has emerged as the recognized world leader in the development, manufacture and commercialization of diagnostic products based on its patented genetic probe technology. Gen-Probe has received over 40 FDA clearances and approvals for genetic probe tests to detect a wide range of microorganisms, including Chlamydia trachomatis, Mycobacterium tuberculosis and Neisseria gonorrhoeae.

8. Many human diseases are caused by bacterial or viral agents that invade living cells. Historically, the presence of these bacterial or viral agents was detected directly by time-consuming methods such as culture or indirectly through the detection of antibodies. Unfortunately, it takes time, sometimes weeks or months, to grow organisms in culture, and it usually takes months for the body to manufacture antibodies in sufficient amounts to reveal the presence of infectious agents. Consequently, these methods do not lend themselves to early detection of infection. NAT addresses this problem.

9. Among the disease detection technologies recently applied by Gen-Probe is its patented nucleic acid technology known as "Transcription-Mediated Amplification" ("TMA"). This technology enables Gen-Probe's NAT products to detect extraordinarily small quantities of the nucleic acids of infectious agents.

10. In September 1996, Gen-Probe received a $7.7 million grant from the National Institutes of Health to develop TMA-based nucleic acid tests to be used in screening donated blood for and human immunodeficiency virus (HIV), the causative agent of AIDS, and hepatitis C virus (HCV), which causes a severe form of hepatitis.

11. At the time of the NIH grant to Gen-Probe, donated blood was principally tested by procedures that detected the presence of antibodies to the viruses being screened. Due to the time it takes for the body to make antibodies after initial infection, donated blood may test negative for antibodies, yet still carry infectious viruses. This delay between the time of actual infection and the time that antibodies can first be detected is often known as the "window period." Reduction of this "window period" was a significant concern of the United States government and the primary focus

of the grant to Gen-Probe to develop NAT diagnostics for use in blood screening.

12. In fulfilling its obligations under the grant, Gen-Probe developed NAT tests to detect the DNA of HIV and hepatitis C in blood. Through the use of its NAT test, Gen-Probe believes that researchers and medical personnel may rapidly and *directly* detect the presence of genetic material of viruses like HIV and HCV more accurately and without the complications and delay associated with conventional *indirect* tests. As such, Gen-Probe believes that its new test may significantly reduce the "window period" for detection of these extremely harmful viral agents and resulting diseases.

13. Final development of the NAT tests for blood screening in the United States is now taking place in testing conducted by the American Red Cross, America's Blood Centers, and others. ("A Purity Quest; Local Biotech's Ultra-Sensitive Blood Screening Could Cut Risk of AIDS, Hepatitis," *San Diego Union*, March 25, 1999, page C-1.) Use of the tests in the United States is made pursuant to an Investigational New Drug Application filed with the United States Food and Drug Administration. In blood tested by the American Red Cross, Gen-Probe's products have detected hepatitis C and HIV which escaped detection by prior methods. ("New Blood Screening Finds Virus Others Missed; Experimental Test Turns Up Hepatitis C In Donated Blood," *San Diego Union*, April 2, 1999, page B-2.)

14. On September 21, 1999, the French Ministry of Health approved the sale of the Gen-Probe blood screening tests in France. Gen-Probe anticipates approval of its tests for us in Australia in early 2000.

15. Gen-Probe has entered into an agreement with Chiron Corporation ("Chiron") of Emeryville, California, with respect to the development, manufacture, and distribution of blood screening products. Gen-Probe is also a party to an agreement with Bayer Corporation ("Bayer") of Emeryville, California with respect to the development, manufacture, and distribution of clinical diagnostic products for the detection of HIV and hepatitis C, among other pathogens.

16. Gen-Probe anticipates that additional clinical trials in the United States of its HIV/HCV tests for use in blood screening and in clinical diagnostics will commence in the first part of 2000. Gen-Probe anticipates the conclusion of those clinical trials, and the initiation of

commercial sales in the United States of kits containing its HIV/HCV blood screening test, during 2000.

17. All of the Gen-Probe products are manufactured in San Diego, California.

THE '338 PATENT

18. Gen-Probe is informed and believes that on or about May 12, 1998, the United States Patent and Trademark Office issued United States Patent No. 5,750,338 ("the '338 patent") based upon Patent Application No. 238,080 filed on May 3, 1994.

19. Gen-Probe is informed and believes that defendant Vysis claims to be the owner, by assignment, of the entire right, title and interest of the '338 patent. The claims of the '338 patent purport to relate to assays and probes for polynucleotide molecules such as DNA and RNA.

20. In early 1999, Vysis informed Gen-Probe that it believed that the '338 patent "applied" to Gen-Probe's NAT blood screening tests for HIV and HCV. Following further discussions and to avoid any complications in Gen-Probe's plans for commercial deployment of its NAT test kits, as of June 22, 1999 Gen-Probe obtained a license ("the License") from Vysis under the '338 patent. Gen-Probe also obtained options to the License for its relationships with Chiron and Bayer.

21. Under the terms of the License, Vysis requires Gen-Probe (and its allied parties if the options are exercised) to make significant financial payments to Vysis as royalties on the sale of any product covered by any valid claims of the '338 patent.

22. Notwithstanding the existence of the License, and as further alleged herein, Gen-Probe believes that the claims of '338 patent are invalid in all material respects. Furthermore, Gen-Probe believes that its NAT blood screening tests do not infringe any valid claim of the '338 patent. As such, Gen-Probe disagrees with Vysis' contention that the claims of the '338 patent "apply" to Gen-Probe's activities and contemplated products. For these same reasons, Gen-Probe contends that it has no obligation to make any royalty payments to Vysis with respect to its present products and activities and any contemplated products and activities that Vysis may later claim infringe the claims of the '338 patent.

23. Gen-Probe has communicated to Vysis its belief that the claims of the '338 patent

are invalid. In support of that belief, Gen-Probe has provided Vysis with information that demonstrates that the claims of the '338 patent are invalid. Gen-Probe has also advised Vysis of its belief that its NAT test kits for use in detecting HCV and HIV in the Nation's blood supply do not and will not infringe any valid claims of the '338 patent.

24. Notwithstanding its receipt of the foregoing information, Vysis persists in its assertion that the claims of the '338 patent are valid and enforceable and that Gen-Probe is obligated to make royalty payments in accordance with the terms of the License.

25. Based upon a long history of litigation between Gen-Probe and Vysis and its affiliates, Gen-Probe reasonably anticipates that should it fail to pay royalties pursuant to the License, Vysis will aggressively attempt to enforce its perceived rights under both the License and the '338 patent by terminating the License and by initiating litigation against Gen-Probe, its allied parties, and customers.

26. An actual case or controversy exists between Gen-Probe and Vysis concerning the validity and infringement of the '338 patent and Gen-Probe's rights and obligations under the License. The determination of the issues presented in this complaint will inure to the greater public benefit and good.

COUNT ONE

NON-INFRINGEMENT OF THE '338 PATENT

27. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

28. Gen-Probe's NAT test kits for use in detecting HCV and HIV in the Nation's blood supply do not and will not infringe any valid claims of the '338 patent.

COUNT TWO

INVALIDITY OF THE '338 PATENT

29. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

30. The claims of the '338 patent are invalid by reason of one or more provisions of Title 35 of the United States Code.

COUNT THREE

DECLARATORY RELIEF

31. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

32. An actual controversy has arisen and now exists concerning the rights and obligations of Gen-Probe pursuant to the terms of the parties' License. Those disputes arise from and their resolution depends upon the federal patent laws.

33. Gen-Probe seeks a declaration of its rights and obligations under the License, particularly in light of the invalidity and non-infringement of the '338 patent and defendant's acts of unfair competition as alleged herein.

COUNT FOUR

UNFAIR COMPETITION

34. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 33 of this complaint.

35. Vysis knows or should know the underlying facts establishing the invalidity of the claims of the '338 patent. In continuing to enforce the claims of the '338 patent, Vysis has acted and continues to act unfairly, inequitably and in bad faith. In addition, Vysis' actions constitute unlawful, unfair or fraudulent business practices under California Business & Professions Code Sections 17200, *et seq.*

36. By reason of the aforementioned acts of unfair competition and unlawful, unfair and fraudulent business practices, Gen-Probe is entitled to damages, as established at time of trial, restitution and injunctive relief.

WHEREFORE, Gen-Probe prays as follows:

1. For declarations:

a. That Gen-Probe's products do not and will not infringe any valid claims of '338 patent;

b. That the claims of the '338 patent are invalid; and

c. Of Gen-Probe's rights and obligations under the parties' License;

2. For a preliminary and permanent injunction enjoining and restraining defendant, its respective officers, agents, servants, employees and attorneys, and all persons acting in concert with them, and each of them:

a. From making any claims to any person or entity that Gen-Probe's products infringe the '338 patent;

b. From interfering with, or threatening to interfere with the manufacture, sale, license, or use of Gen-Probe's products by Gen-Probe, its allied parties, distributors, customers, licensees, successors or assigns, and others; and

c. From instituting or prosecuting any lawsuit or proceeding, placing in issue the right of Gen-Probe, its allied parties, distributors, customers, licensees, successors or assigns, and others to make, use or sell Gen-Probe's products;

3. For recovery of Gen-Probe's damages, as proven at time of trial, and restitution of any sums by which Vysis has been unjustly enriched;

4. For recovery of Gen-Probe's attorneys' fees and costs of suit incurred herein; and

5. For such other and further relief as the Court may deem just and proper.

Dated: January 25 1999

COOLEY GODWARD LLP
STEPHEN P. SWINTON (106398)
JAMES DONATO (146140)

By: _____
Stephen P. Swinton

Attorneys for Plaintiff
Gen-Probe Incorporated

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Attorneys for Defendant VYSIS, INC.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE, INCORPORATED, Plaintiff, v. VYSIS, INC., Defendant.	Case No.: 99CV 2668H (AJB) NOTICE OF MOTION AND MOTION BY DEFENDANT VYSIS, INC. FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, TO DISMISS COUNT FOUR OF THE FIRST AMENDED COMPLAINT UNDER FEDERAL RULE OF CIVIL PROCEDURE § 12(b)(6) Date: April 10, 2000 Time: 10:30, a.m. Place: Courtroom 1

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on April 10, 2000, at 10:30 a.m., or as soon thereafter as this matter may be heard before the Honorable Marilyn Huff in Courtroom 1 of the above-entitled Court, located at 940 Front Street, San Diego, defendant Vysis, Inc. ("Vysis") will, and hereby does, move the Court for an order staying the above-captioned action, with the exception that plaintiff be required to

timely respond to the first set of interrogatories served by Vysis on January 26, 2000, pending completion by the United States Patent and Trademark Office ("PTO") of the reissue proceeding for United States Patent No. 5,750,338 ("the '338 patent"), the patent in suit in this action. The application for reissue of the `338 patent was filed March 8, 2000, in the PTO.

Alternatively, defendant Vysis will, and hereby does, move the Court under Federal Rule of Civil Procedure 12(b)(6) for an order dismissing Count Four of the First Amended Complaint in this action, which purports to state a claim for violation of California Business and Professions Code sections 17200 et seq. The grounds for this alternative motion are that Count Four fails to allege facts which state a claim upon which relief can be granted.

The motion for stay will be based on this notice, the attached memorandum of points and authorities, and associated exhibits, the declaration of John H. L'Estrange, Jr., the pleadings, files and records in this case, and any oral and documentary evidence that may be presented at the hearing on this motion.

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The alternative Rule 12(b)(6) motion to dismiss Count Four will be based on this notice, the accompanying memorandum of points and authorities, the pleadings (including the license contract referred to in the first amended complaint) files and records in this case, and any oral argument that may be presented at the hearing on this alternative motion.

Respectfully submitted,

FINNEGAN HENDERSON FARABOW DUNNER & GARRETT, LLP

-and-

WRIGHT & L'ESTRANGE

Dated: March 9, 2000

By: John H. L'Estrange, Jr.
John H. L'Estrange, Jr.
One of the attorneys for
Defendant Vysis, Inc.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE, INCORPORATED, Plaintiff, v. VYSIS, INC., Defendant.	Case No.: 99CV 2668H (AJB) MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF VYSIS MOTION TO FOR A STAY PENDING COMPLETION OF REISSUE PROCEEDINGS AND, ALTERNATIVELY, TO DISMISS COUNT FOUR OF THE FIRST AMENDED COMPLAINT UNDER FED. R. CIV. P. 12(b)(6) Date: April 10, 2000 Time: 10:30 a.m. Place: Courtroom 1

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I. INTRODUCTION

Effective June 22, 1999, Gen-Probe Incorporated ("Gen-Probe") took a license under Vysis', Inc.'s United States Patent No. 5,750,338 ("the '338 patent"). See First Amended Complaint ¶ 20. On December 22, 1999, Gen-Probe filed a Complaint against Vysis, requesting this Court to declare the '338 patent 9 (Ex. A)[1] invalid and not infringed by Gen-Probe's Nucleic Acid Test "NAT" kits. On January 6, 2000 (at Vysis' request), Gen-Probe identified six technical publications that it contended invalidated the '338 patent (Ex. B). None of these publications appears to describe processes where nucleic acid targets are first separated from a patient sample and then subjected to an in vitro amplification process where many copies of each target molecule are made. This was the focus of all of the examples of the '338 patent, and of the United States Patent and Trademark Office ("PTO") in deciding to issue the '338 patent. It is also an essential feature of Gen-Probe's "NAT" test kits. On January 19, 2000, Vysis (at Gen-Probe's request) informed Gen-Probe that it would answer the Complaint in this action (Ex. C).

In response, on January 25, 2000, Gen-Probe filed a First Amended Complaint again requesting the Court to declare the '338 patent invalid and not infringed by Gen-Probe's NAT test kits, and, additionally, to declare Gen-Probe's rights and obligations under the License between Gen-Probe and Vysis pertaining to the '338 patent (pertinent portions of which are attached as Ex. D), and charging Vysis with unfair competition and violation of Cal. Bus. & Prof. Code § 17200 *et seq.* See First Amended Complaint, Count Four.

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[1]All exhibits referred to in this memorandum are attached to and authenticated by the Declaration of John H. L'Estrange, Jr. filed this same date.

In an effort to secure a speedy, inexpensive and just resolution of the patent validity issues raised by Gen-Probe, Vysis filed on March 8, 2000, an application with the PTO to reissue the '338 patent under 35 U.S.C. § 251 (Ex. E). Vysis identified the publications cited by Gen-Probe for the PTO so that their effect, if any, on the existing claims may be determined. Additionally, Vysis has presented narrower claims that clearly avoid Gen-Probe's publications yet still clearly cover Gen-Probe's products.

As more fully set forth in Section II below, this action should be stayed pending the outcome of the reissue proceedings[2] so that the Court and the parties may have the benefit of the PTO's views on the issues raised by Gen-Probe and so that any newly issued patent claims can be made a part of this action.

Alternatively, for reasons noted in Section III below, Gen-Probe's claim for unfair competition should be dismissed under Fed. R. Civ. P. 12(b)(6) as failing to state a claim upon which relief can be granted. If the motion for a stay is granted the Rule 12(b)(6) motion to dismiss Count Four may be deferred until after the stay is vacated by the Court.

[2]Reissue is essentially a reprosecution of the patent. The patentee may include for examination in the reissue application: (i) unchanged, original claims; (ii) new, narrower claims; and (iii) if the reissue is filed within two years of the grant of the patent, new, broader claims. A reissue application is examined in the same manner as original applications; original claims may therefore be rejected, and new claims may be allowed. See 35 U.S.C. § 1.176.

II. THE LITIGATION SHOULD BE STAYED PENDING RESOLUTION OF REISSUE PROCEEDINGS FOR THE '338 PATENT

Gen-Probe alleges that the '338 patent is invalid. Specifically, at paragraph 23 of its First Amended Complaint, Gen-Probe asserts that:

> 23. Gen-Probe has communicated to Vysis its belief that the claims of the '338 patent are invalid. In support of that belief, Gen-Probe has provided Vysis with information that demonstrates that the claims of the '338 patent are invalid.

Vysis believes that the information that Gen-Probe has cited does not invalidate the '338 patent. However, in the interests of judicial economy, Vysis has requested the PTO to reissue the '338 patent. Specifically, Vysis has asked the PTO to allow additional, narrower claims, which clearly avoid the art cited by Gen-Probe and which still cover Gen-Probe's activities. In doing so, the PTO will review the '338 patent in view of the information which Gen-Probe has provided to Vysis. To avoid substantial duplication of effort in determining the patent's validity, and to avoid potentially wasted investment in analyzing claims for infringement (a) which may or may not be altered during reissue, and (b) which may come into existence only following the reissue process, Vysis moves this court to stay the litigation proceedings pending the outcome of the reissue proceedings in the PTO.

Granting a stay is well within the Court's discretionary power to manage its docket. *Ethicon, Inc. v. Quigg,* 849 F.2d 1422, 1426-27 (Fed. Cir. 1988) Courts routinely grant stays during reissue applications for just this purpose. *Clintec Nutrition Co. v. Abbott Labs.,* No. 94-C3152, 1995 WL 228988, at *6 (N.D. Ill. Apr. 14, 1995) (motion to stay pending outcome of reissuance proceedings granted); *see also ASCII Corp. v. STD Entertainment USA, Inc.*, 844 F. Supp.

1378, 1380-81 (N.D. Cal. 1994) (The court has the inherent ability to grant a stay of proceedings; motion to stay pending outcome of reexamination or reissue proceedings granted).

In deciding a motion to stay, courts generally consider: (a) whether doing so would cause undue prejudice or present a clear tactical disadvantage to the non-moving party (*ASCII*, 844 F.Supp. at 1380); and (b) whether the stay will result in a simplification or a complication of the issues, proof and questions of law (*Clintec*, 1995 WL at *1 (*citing, Teradyne, Inc. v. Hewlett-Packard Co.*, No. 91-C-0344, 1993 U.S.Dist. LEXIS at *21 (N.D. Cal. Jan. 7, 1993)). In this matter, the Court's consideration of whether to grant a stay should also be informed by the terms and purposes of the Declaratory Judgment Act. *See United Sweetener USA, Inc. v. Nutrasweet Co.*, 766 F.Supp. 212, 215-16 (D. Del. 1991). All factors weigh in favor of a stay.

A. A Stay Would Not Cause Undue Prejudice To Gen-Probe

A stay would not cause undue hardship because (a) little investment has been made by either party in this litigation; (b) reissue proceedings are "special" *(Manual of Patent Examining Procedure* (hereinafter "MPEP"), § 1442) and thus the PTO expedites their processing (MPEP § 1442,03); and (c) Gen-Probe can file a protest in the PTO expressing its views on the validity of the '338 patent (37 C.F.R. § 1.291).

With respect to the interest of the parties in the current litigation, the action is barely a few months old, Vysis has not answered the complaint, there has been no Early Neutral Evaluation Conference, neither party has responded to discovery requests, a pre-trial order has not been submitted and will not be submitted for some time, and a trial date has not been set. See *ASCII*, 844 F.Supp at

1381 (no undue prejudice and motion to stay granted where parties were only in initial stages of lawsuit, undertaken little or no discovery, and case had not been set for trial); *Dennco, Inc. v. Cirone*, No. 94-455-SD (no undue prejudice and motion to stay granted where the parties were in the initial stages of the lawsuit and had undertaken little or no discovery); *Clintec, 1995 WL, at *3* (no undue prejudice and motion to stay granted where suit was filed about one year prior, two depositions had been taken, some paper discovery had occurred, but no trial date was set).

Reissue proceedings would not cause undue hardship for the further reason that the PTO expedites the processing of such applications, placing great emphasis on the expedited processing of reissue applications which are the subject of a stayed litigation. MPEP § 1442.03. All reissue applications are taken up "special", and are also taken up ahead of all other "special" applications. MPEP § 1442. Special applications are responded to immediately. Id. Finally, unlike other applications for which applicants have up to six months to respond to PTO actions, reissue applicants only receive one month to respond to PTO actions and this time period may be extended only upon a showing of clear justification. MPEP § 1442.01; 37 C.F.R. 1.136(b). Finally, grant of stay pending resolution of the reissue proceedings will not cause undue prejudice because Gen-Probe can provide the PTO with its view on the validity of the '338 patent through an appropriate protest. 37 C.F.R. § 1.291; MPEP § 1901.

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B. A Stay Would Result In A Simplification Of The Issues, Proof, And Questions Of Law

A stay would serve the interests of judicial economy. Patent validity, a core issue in the reissue proceeding, is also a central issue in this litigation. Grant of a stay would serve the interests of judicial economy by preventing the substantial duplication of effort that would occur if this case proceeded conjunctively with the reissue proceeding. *See GPAC, Inc. v. D.W.W. Enterprises, Inc.*, 144 F.R.D. 60, 64, (D.N.J. 1992). In addition, by shifting to the PTO the initial decision on patent validity, the outcome of the reissue proceeding would facilitate settlement without further use of the court. *See id.; United Merchants Mfrs., Inc.*, 495 F.Supp.444,447 (N.D.Ga. 1980); *Fisher Controls Co., Inc. v. Control Components, Inc.*, 443 F.Supp. 581, 582 (S.D. Iowa 1977) At worst, the litigation would proceed afterwards with the court having the benefit of the PTO's expertise in evaluating validity in view of prior art references. In this regard, a stay will minimize the prospect of the Court having to deal with validity defenses that have not been initially passed upon by the PTO. *See GPAC*, 144 F.R.D. at 65; *see also ASCII*, 844 F.Supp. at 1381 ("[T]he court concludes that ASCII should be given the opportunity to file an application for reexamination and/or reissue, since the USPTO's expertise may assist both the parties and the court. . . ."); *Gould v. Control Laser Corp.*, 705 F.2d 1340, 1342 (Fed. Cir. 1983)("One purpose of the reexamination [or reissue] procedure is . . . to facilitate trial of [validity] by providing the district court with the expert view of the PTO. . . .").

Additional benefits of a stay which courts have recognized, and are applicable to the case at hand, include: (a) Many discovery

problems relating to the prior art can be alleviated by the PTO examination; (b) The record of reissue would likely be entered at trial, thereby reducing the complexity and length of the litigation; (c) Issues, defenses, and evidence will be more easily limited in pre-trial conferences after a reissue; and (d) The cost will likely be reduced both for the parties and the court. *See GPAC,* 144 F.R.D. at 63; *Clintec,* 1995 WL, at *2; *United Merchants and Mfrs.,* 495 F.Supp. at 447; *Fisher Controls Co., Inc.,* 443 F.Supp. at 582.

C. A Stay Is Particularly Appropriate In A Declaratory Judgment Proceeding

The Declaratory Judgment Act is an authorization for jurisdiction, not a command. *United Sweetener,* 766 F.Supp. at 216 (*quoting Erbamont, Inc. v. Cetus Corp.,* 720 F.Supp. 387, 392 (D. Del. 1990)). Under the Act, courts should refuse to proceed if they find that a declaratory judgment action will not serve a useful purpose or is otherwise undesirable. *United Sweetener,* 766 F.Supp. at 216 (*quoting Erbamont, Inc. v. Cetus Corp.,* 720 F.Supp. 387, 392 (D. Del. 1990)). In determining the appropriateness of a declaratory judgment action, courts should consider whether such an action would clarify and settle the legal relations in issue, and whether such an action would terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the action.

As discussed above, staying this litigation in favor of the PTO proceedings would simplify issues and evidence and may moot the litigation altogether by promoting settlement. Accordingly, it would be entirely consistent with the discretionary nature of declaratory judgment jurisdiction to condition the exercise of that jurisdiction on a stay pending completion of the reissue proceedings.

In this regard, Vysis respectfully requests that Gen-Probe be ordered to timely answer Vysis' First Set of Interrogatories, served January 26, 2000, (Ex. F), notwithstanding the entry of the stay. Those interrogatories simply seek the bases for Gen-Probe's allegations of invalidity and noninfringement. The answers are necessary for the Court and the parties to gain the full benefit of the reissue proceedings. Gen-Probe's letter informing Vysis of the publications allegedly invalidating the '338 patent explicitly stated that there are other such materials of which Gen-Probe is aware (Ex. B). If there are additional validity or claim interpretation issues now known to Gen-Probe, Gen-Probe should identify them so that the PTO's reissue procedures can be as complete as possible. The discovery request was timely served and, but for Gen-Probe's request for an extension of time to answer in exchange for the extension granted Vysis to respond to the amended complaint, would already have been answered.[3]

III. THE UNFAIR COMPETITION CLAIM SHOULD BE DISMISSED UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6)

Vysis respectfully moves the Court, in the alternative, for an order dismissing Gen-Probe's unfair competition allegations set forth in Count Four of the First Amended Complaint for failure to state a claim for which relief can be granted. Fed. R. Civ. P. 12(b)(6). The alleged act of unfair competition is stated in paragraph 35 of the First Amended Complaint as follows:

> 35. Vysis knows or should know the underlying facts establishing the invalidity of the claims of the '338 patent. In continuing to enforce the claims of the '338

[3]This Court's Order dated February 8, 2000, requires Gen-Probe to respond by March 27, 2000.

> patent, Vysis has acted and continues to act unfairly, inequitably and in bad faith. In addition, Vysis' actions constitute unlawful, unfair or fraudulent business practices under California Business & Professions Code Sections 17200, *et seq.*

The apparent antecedent for the acts of "continuing to enforce the claims of the '338 patent" is stated in paragraphs 23 and 24 as follows:

> 23. Gen-Probe has communicated to Vysis its belief that the claims of the '338 patent are invalid. In support of that belief, Gen-Probe has provided Vysis with information that demonstrates that the claims of the '338 patent are invalid. Gen-Probe has also advised Vysis of its belief that its NAT test kits for use in detecting HCV and HIV in the Nation's blood supply do not and will not infringe any valid claims of the '338 patent.
>
> 24. Notwithstanding its receipt of the foregoing information, Vysis persists in its assertion that the claims of the '338 patent are valid and enforceable and that Gen-Probe is obligated to make royalty payments in accordance with the terms of the License.

Gen-Probe does not allege that the license contract is not a valid contract. The contract provides that royalties shall be paid unless and until a licensed patent claim is declared invalid in a final decision from a tribunal of competent jurisdiction. This is in accord with the substantive patent law, which provides that (a) a patent is presumed valid (35 U.S.C. § 282); (b) the party asserting invalidity has the burden of proving that the patent is invalid by clear and convincing evidence (*Ryco Inc. v. Ag-Bag* Corp. 857 F.2d 1418, 1423 (Fed. Cir. 1988)); and (c) a licensee wishing to retain the benefits of a patent license must continue to pay royalties until the presumptively valid patent is declared invalid (*Cordis Corp. v. Medtronic, Inc.*, 780 F.2d 991, 994-95 (Fed. Cir. 1985)). Thus, Vysis' alleged persistence in its belief that the patent remains valid and enforceable and that Gen-Probe is obligated to make royalty payments in accordance with the terms of the license is simply

declaratory of Gen-Probe's obligations under a valid contract. Section 17200 cannot convert activity authorized by law into a tort. *Cel-Tech Communications, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal.4th 163, 182 (1999).

Moreover, the license contract may be terminated unilaterally by Gen-Probe in accordance with the terms of the agreement (Ex. D). Vysis cannot, therefore, be forcing Gen-Probe to be a licensee or to perform any of the obligations under the license contract.

If the asserted invalidity or noninfringement of the '338 patent is as clear as Gen-Probe would have this Court believe, Gen-Probe may terminate the license, thereby freeing itself from its royalty obligations thereunder. If, on the other hand, the outcome of its declaratory judgment action on validity and infringement of the '338 patent is sufficiently unclear that Gen-Probe wishes to maintain its rights under the license in the event of an adverse judgment, then the continued existence of the license agreement, with the associated obligation to abide by its terms, can hardly constitute an act of unfair competition. The decision of whether or not to remain a licensee is entirely Gen-Probe's. Gen-Probe cannot blame Vysis for the logical consequences of Gen-Probe's unilateral decision to remain a licensee.

Finally, if Gen-Probe is implying that Vysis' decision to defend itself in this lawsuit is the act of "enforcement" constituting unfair competition, this action is specifically authorized under the litigation privilege of California Civil Code § 47(b) and cannot, therefore, constitute unfair competition. *Cel-Tech*, 20 Cal.4th at 182-3 (*referring to Rubin v. Green*, 4 Cal.4th 1187 (1993)); *see also California Physicians' Service v. Superior Court*, 9 Cal.App.4th 1321, 1325 (1992) ("[t]here is no tort of 'malicious defense.' The

mainstay supporting this principle is the absolute privilege contained in Civil Code section 47, subdivision (b).") (1992). The only exception to California's litigation privilege under Section 47(b) is malicious prosecution. Rubin, 4 Cal.4th at 1193-94, However, Gen-Probe cannot allege malicious prosecution for at least two reasons. First, Vysis is defending this action, not prosecuting it, and as noted, no tort for "malicious defense" exists. *Triplett v. Farmers Ins. Exchange*, 24 Cal.App.4th 1415, 1422 (1994). Second, to prove malicious prosecution, Gen-Probe needs to show favorable termination of the underlying action, which it cannot do, or even plead, prior to resolution of its declaratory judgment action on the patent validity and liability issues.

In view of the foregoing, Gen-Probe's unfair competition claims should be dismissed under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted.

IV. CONCLUSION

For the reasons discussed above, Vysis respectfully requests that this Court grant its motion to stay in this litigation, pending the outcome of the reissue proceedings at the PTO (with the exception that Gen-Probe be required to timely respond to the first set of interrogatories served by Vysis); and, alternatively, to dismiss

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Count Four of the First Amended Complaint for failure to state a claim for which relief can be granted.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

-and-

WRIGHT & L'ESTRANGE

Dated: March 9, 2000

By: John H. L'Estrange, Jr.
John H. L'Estrange, Jr.
One of the attorneys for Defendant Vysis, Inc.

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Attorneys for Defendant VYSIS, INC.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE, INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

Case No.: 99CV 2668H (AJB)

DECLARATION OF JOHN H. L'ESTRANGE, JR. IN SUPPORT OF MOTION BY DEFENDANT VYSIS, INC. FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE § 12(b)(6)

Date: April 10, 2000
Time: 10:30 a.m.
Place: Dept. 1

I, John H. L'Estrange, Jr., declare as follows:

1. I am a member in good standing of the state bar of California, and a partner in the law firm Wright & L'Estrange, counsel for Defendant Vysis, Inc. ("Vysis") in the above-captioned proceeding. I make this declaration, based on information and belief, in support of the motion by Vysis for a stay of proceedings and, alternatively, to dismiss Count Four of the First Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

2. Attached hereto as Exhibit A is a true and correct copy of United States Patent No. 5,750,338 ("the '338 patent")

3. Attached hereto as Exhibit B is a true and correct copy of a letter dated January 6, 2000, from Peter Shearer, Vice President for Intellectual Property for Gen-Probe Incorporated to Norval Galloway, counsel for Vysis.

4. Attached hereto as Exhibit C is a true and correct copy of a letter dated January 19, 2000, from Norval Galloway, to Peter Shearer.

5. Attached hereto as Exhibit D is a redacted copy of the license agreement which is alleged in paragraph 20 of the First Amended Complaint in the above captioned action.

6. Attached hereto as Exhibit E a true and correct copy of the application to the United States Patent and Trademark Office ("PTO") filed to reissue the '338 patent. This application was filed with the PTO on March 8, 2000.

7. Attached hereto as Exhibit F is a true and correct copy of the first set of interrogatories personally served by Vysis on Gen-Probe on January 26, 2000. The stipulated order of this court dated February 8, 2000, provides that Gen-Probe's responses to Vysis' first set of interrogatories are due on or before March 27, 2000.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information and belief.

Executed this 9th day of March, 2000, at San Diego, California.

John H. L'Estrange, Jr.